

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GREGORY R. HECK, MARIANNE MALVEN,
JAMES D. MASUCCI, and JINSONG YOU

Appeal 2008-2875
Application 10/925,392
Technology Center 1600

Decided: September 16, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1, 3-12 and 19.¹ We have jurisdiction under 35 U.S.C. § 6(b).

¹ This appeal was heard on August 13, 2008.

STATEMENT OF THE CASE

The “invention relates to the field of plant molecular biology and plant genetic engineering and polynucleotide molecules useful for the expression of transgenes in plants.” (Spec. 1.)

The claims are directed to an isolated polynucleotide having gene regulatory activity, as well as DNA constructs containing the polynucleotide, and transgenic plants transformed with the DNA construct. Claims 1 and 3 are representative of the claims on appeal, and read as follows:

1. An isolated polynucleotide molecule having gene regulatory activity and comprising a sequence selected from the group consisting of a polynucleotide sequence comprising at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1 and a polynucleotide sequence comprising at least 98% identity to the polynucleotide sequence of SEQ ID NO: 1.
3. The isolated polynucleotide molecule according to claim 1, wherein said isolated polynucleotide molecule comprises a polynucleotide sequence which exhibits at least about 98% identity with the polynucleotide sequence of SEQ ID NO: 1.

We reverse.

ISSUE (Indefiniteness)

The Examiner contends that the phrase “at least about” renders claim 3 indefinite.

Appellants contend that the Examiner has misinterpreted the claim.

Thus, the issue on appeal is: Is the Examiner's interpretation of claim 3 correct such that the use of the phrase "at least about" renders claim 3 indefinite?

FINDINGS OF FACT

FF1 The Examiner rejects claim 3 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Appellants regard as the invention (Ans. 5).

FF2 The Examiner asserts, citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991), that the phrase "at least about" renders the claim indefinite (Ans. 5).

PRINCIPLES OF LAW

Claims are in compliance with 35 U.S.C. § 112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1987). However, "breadth is not to be equated with indefiniteness." *In re Miller*, 441 F.2d 689, 693 (CCPA 1971); *see also In re Hyatt*, 708 F.2d 712, 714-15, (Fed. Cir. 1983).

Moreover, under 35 U.S.C. § 112, third paragraph, a "claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in

dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.”

ANALYSIS

In *Amgen*, the Federal Circuit found “at least about” to be indefinite given the use of the term “about” coupled with the amount of error inherent in the assay for measurement of specific activity, as well as the fact that there was close prior art. *Amgen*, 927 F.2d at 1218. The court cautioned that the holding “should not be understood as ruling out any and all uses” of “about,” as “[i]t may be acceptable in appropriate fact situations.” *Id.*

Claim 3 is dependent from claim 1, and thus incorporates all of the limitations of claim 1, thus further limiting it. Claim 1 is drawn to “an isolated polynucleotide molecule” wherein the molecule is selected from the Markush group of either “a sequence selected from the group consisting of a polynucleotide sequence comprising at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1” or “a polynucleotide sequence comprising at least 98% identity to the polynucleotide sequence of SEQ ID NO: 1.” As claim 3 recites that the polynucleotide molecule “comprises a polynucleotide sequence which exhibits at least about 98% identity with the polynucleotide sequence of SEQ ID NO: 1,” it cannot further limit the second member of the Markush group, *i.e.*, “a polynucleotide sequence comprising at least 98% identity to the polynucleotide sequence of SEQ ID NO: 1,” as it would in fact broaden the breadth of that member of the Markush group. Thus, it must modify the first member of the Markush

group, that is “a sequence selected from the group consisting of a polynucleotide sequence comprising at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1.” The polynucleotide molecule of claim 3 therefore must comprise at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1 as well as being at least about 98% identical with the polynucleotide sequence of SEQ ID NO: 1 (*see also* Reply Br. 17). As sequence identity can be precisely determined, and the fact that the polynucleotide molecule of claim 3 must comprise at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1, we find that the skilled artisan would understand the meets and bounds of claim 3.

CONCLUSIONS OF LAW

Thus, we conclude that claim 3 is definite under 35 U.S.C. § 112, second paragraph, and the rejection is reversed.

ISSUE (WRITTEN DESCRIPTION)

The Examiner contends that claims 1, 3-12, and 19 do not comply with the written description requirement of 35 U.S.C. § 112, first paragraph, as the genus encompassed by the claims is very large (Ans. 6).

Appellants contend that the Specification supports that Appellants were in possession of the full scope of the invention (App. Br. 9).

Thus, the issue on appeal is: Whether the disclosure as filed demonstrates that Appellants were in possession of the subject matter of claims 1, 3-12, and 19?

FINDINGS OF FACT

FF3 Claims 1, 3-12, and 19 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 6).

FF4 The Examiner finds that the “essential feature of the claimed polynucleotide is that it has ‘gene regulatory activity.’ However, the specification has not provided any specific structures or subsequences that are associated with this essential function.” (Ans. 6.)

FF5 The Examiner finds further that the genus of sequences encompassed by the claims is very large, finding that the genus may encompass 7.7×10^{25} or larger molecule (Ans. 6-7).

FF6 Thus, according to the Examiner:

Given the extremely large genus encompassed by the claims with only one of the species reduced to practice, and given the total lack of any description of a structure/function relationship between certain subsequences of SEQ ID NO:1 and the function of having gene regulatory activity, the requirement for written description has not been met.

(Ans. 7.)

PRINCIPLES OF LAW

“The burden of showing that the claimed invention is not described in the application rests on the PTO in the first instance.” *In re Edwards*, 568 F.2d 1349, 1354 (CCPA 1978). A written description of an invention involving a nucleic acid, like a description of a chemical genus, “requires a precise definition, such as by structure, formula, [or] chemical name,” of the claimed subject matter sufficient to distinguish it from other materials.

Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993). While “examples explicitly covering the full scope of the claim language” are not typically required, a sufficient number of representative species must be included “to demonstrate that the [applicants] possesses the full scope of the invention.”

LizardTech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005). However,

the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.

Capon v. Eshhar, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

ANALYSIS

Appellants argue that they “have explicitly taught the structure of the promoter sequences by providing the nucleic acid sequence of SEQ ID NO:1, a sequence provided with the application as filed.” (App. Br. 10.) According to Appellants, “[w]hile the claims encompass fragments of the sequence SEQ ID NO:1 and sequences with at least . . . 98% identity with SEQ ID NO:1, these groups define a subset of sequences fully described by SEQ ID NO:1.” (*Id.*)

We agree. Claim 1, the broadest claim on Appeal, recites an “isolated polynucleotide molecule having gene regulatory activity and comprising a sequence selected from the group consisting of a polynucleotide sequence comprising at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1 and a polynucleotide sequence comprising at least 98%

identity to the polynucleotide sequence of SEQ ID NO: 1.” As to “a polynucleotide sequence comprising at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1,” structure is provided, *i.e.*, 1000 contiguous bases of SEQ ID NO: 1, a sequence that is 2190 nucleotides long, and also knows the function, promoter activity. As to sequences that have “at least 98% identity to the polynucleotide sequence of SEQ ID NO: 1,” the same analysis applies, that is, the skilled artisan would know the structure, *i.e.* at least 98% identity to SEQ ID NO: 1, as well as the function, having promoter activity.

CONCLUSION

Thus, we find that claims 1, 3-12, and 19 comply with the written description requirement of 35 U.S.C. § 112, first paragraph, and the rejection is reversed.

ISSUE (ENABLEMENT)

The Examiner contends that the Specification fails to enable claims 1, 3-12, and 19 as required by 35 U.S.C. § 112, first paragraph.

Appellants contend that the claims are enabled by the Specification (App. Br. 14).

Thus, the issue on Appeal is: does the Specification enable claims 1, 3-12, and 19 as required by 35 U.S.C. § 112, first paragraph?

FINDINGS OF FACT

FF7 The Examiner rejected claims 1, 3-12, and 19 under 35 U.S.C. § 112, first paragraph, on the grounds that “the specification, while being enabling for an isolated polynucleotide molecule comprising SEQ ID NO: 1 and for polynucleotides comprising at least 1000 contiguous bases of SEQ ID NO:1, does not reasonably provide enablement for an isolated polynucleotide molecule comprising a sequence which has at least 98% identity, at least about 98% identity, or at least 99% identity with SEQ ID NO:1.” (Ans. 7-8.)

FF8 The Examiner made the following findings with respect to the factors set out in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).²

FF9 *The breadth of the claims*: The Examiner notes that claims “1, 3, and 19 are broadly drawn to an isolated polynucleotide molecule having gene regulatory activity and having at least 98% identity, or at least about 98% identity, or at least 99% identity with SEQ ID NO:1.” (Ans. 8.)

FF10 *Nature of the invention and the state of the prior art*: The Examiner notes that the “nature of the invention is the construction of a chimeric promoter for use in plants.” (Ans. 8.)

FF11 *The amount of direction or guidance presented and the existence of working examples*: According to the Examiner while the Specification teaches that a chimeric promoter, presumably SEQ ID NO:1, was cloned into two different expression vectors to drive expression of two different

² The factual considerations discussed in *Wands* are: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

marker genes, it “has not taught any polynucleotides with 98% identity or ‘about’ 98% identity or 99% identity to SEQ ID NO:1 that have gene regulatory activity.” (Ans. 8-9.)

FF12 *The relative skill of those in the art, the predictability or unpredictability of the art, and the quantity of experimentation necessary:*

The Examiner, citing Donald³ and Kim,⁴ states that the prior art demonstrates “that mutation of promoter sequences produces unpredictable results,” and that “[e]ven minor alterations can alter promoter activity.” (Ans. 9.)

PRINCIPLES OF LAW

“When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application.” *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

“[T]o be enabling, the specification . . . must teach those skilled in the art how to make and use *the full scope of the claimed invention* without ‘undue experimentation.’” *Id.* at 1561, (emphasis added), *quoted in Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997).

³ Donald, “Mutation of either G box or I box sequences profoundly affects expression from the Arabidopsis rbcS-1a promoter,” *The EMBO J.*, Vol. 9, pp. 1717-1726 (1990).

⁴ Kim, “A 20 nucleotide upstream element is essential for the nopaline synthase (*nos*) promoter activity,” *Plant Molecular Biology*, Vol. 24, pp. 105-117 (1994).

Thus, “there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed.” *In re Vaeck*, 947 F.2d 488, 496 & n. 23 (Fed. Cir. 1991), *quoted in Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 (Fed. Cir. 1999). Some experimentation, even a considerable amount, is not “undue” if, e.g., it is merely routine, or if the specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

ANALYSIS

The Examiner concludes:

In the absence of this guidance, one skilled in the art is left to randomly produce an endless number of substitutions or deletions of nucleotides from SEQ ID NO:1, and test each new molecule for having gene regulatory activity, which is undue experimentation. Given the breadth of the claims encompassing any polynucleotide have 98% identity, “about” 98% identity, or 99% identity to SEQ ID NO:1, and given unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would have been required by one skilled in the art to make and use the claimed invention.

(Ans. 9.)

Appellants argue that it is well within the level of ordinary skill in the art to prepare nucleic acid sequences that are 98% identical to SEQ ID NO: 1 (App. Br. 15). Moreover, the Specification teaches the preparation of derivatives of full length promoter sequences, as well as methods of determining the activity of such promoter sequences (*id.*). As to Kim and

Donald, while Appellants acknowledge that the “some deletions and mutations will reduce activity of a promoter,” both references “employ standard screening methods to assess the promoter activity of sequences comprising deletions and/or point mutations.” (App. Br. 18-19.)

We agree. Even if we were to assume that the amount of experimentation to practice the full scope of the claimed invention might be extensive, such experimentation would have been routine. The art cited by the Examiner demonstrates the routine nature of promoter analysis, since both Donald and Kim use standard methods to determine which sequence elements affect promoter strength and which elements have no impact. The methods for performing such screening were provided by the Specification, and were also well known to those skilled in the art. *See, e.g., Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998) (“test [for undue experimentation] is not merely quantitative ... if it is merely routine”); *Ex parte Kubin*, 83 USPQ2d 1410, 1416 (Bd. Pat. App. & Int. 2007). Thus, we conclude the Specification provides an enabling disclosure.

CONCLUSIONS OF LAW

We thus conclude that the Specification enables claims 1, 3-12, and 19 as required by 35 U.S.C. § 112, first paragraph, and the rejection is reversed.

ISSUE (Anticipation)

The Examiner contends that polynucleotide molecule of claim 3 is anticipated by Brevario.⁵

Appellants contend that “because claim 3 is more narrow than claim 1 and claim 1 is acknowledged to define over the art, the rejection is without merit.” (Reply Br. 17.)

Therefore, the issue on appeal is: Has the Examiner established that the polynucleotide molecule of claim 3 is anticipated by the sequence of Brevario?

FINDINGS OF FACT

FF13 Claim 3 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Brevario.

FF14 Claim 3 is dependent from claim 1, but claim 1 was not rejected.

FF15 Brevario is cited for teaching a sequence of a partial tubA2 gene that comprises 93.8% identity with SEQ ID NO: 1 (Ans. 10).

PRINCIPLES OF LAW

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

ANALYSIS

As noted above in the indefiniteness analysis, the polynucleotide molecule of claim 3 must comprise at least 1000 contiguous bases of the

⁵ Brevario, GenBank Accession AJ488063 (2002).

polynucleotide sequence of SEQ ID NO: 1 as well as being at least about 98% identical with the polynucleotide sequence of SEQ ID NO: 1. As the Examiner has not made any findings that the sequence of Brevario comprises comprise at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1, and apparently does not do so as claim 1 was not included in the rejection, the Examiner has not established that the sequence of Brevario meets all of the limitations of claim 3, and thus has not set forth a prima facie case that Brevario anticipates claim 3.

CONCLUSION

We therefore find that the Examiner has failed to establish that the polynucleotide molecule of claim 3 is anticipated by the sequence of Brevario, and the rejection is reversed.

SUMMARY

Because the Examiner has failed to set forth a prima facie case of patentability as to any of the claims on appeal, all of the rejections on appeal are reversed.

REVERSED

Ssc:

SONNENSCHN NATH & ROSENTHAL LLP
P.O. BOX 061080

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SOUTH WACKER DRIVE STATION
SEARS TOWER
CHICAGO, IL 60606